IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PHARMASTEM THERAPEUTICS, INC.,	)	
Plaintiff,	)	
v.	)	C.A. No. 02-148 GMS
VIACELL INC., CRYO-CELL INTERNATIONAL, INC., CORCELL, INC., STEMCYTE, INC., CBR SYSTEMS, INC. f/k/a CORD BLOOD REGISTRY, INC., BIRTHCELLS TECHNOLOGY, INC., NUSTEM TECHNOLOGIES, INC., and BIO-CELL, INC.,	)	
Defendants.	)	

MEMORANDUM AND ORDER

I. INTRODUCTION

On August 5, 2003, PharmaStem Therapeutics, Inc. ("PharmaStem") filed a motion *in limine* to exclude from evidence the July 21, 1999 decision of the European Patent Office ("EPO") revoking one of PharmaStem's related European patents (the "EPO Decision"). On August 12, 2003, Viacell Inc., Cryo-Cell International, Inc., Corcell, Inc., Stemcyte, Inc., CBR Systems, Inc. f/k/a Cord Blood Registry, Inc., Birthcells Technology, Inc., Nustem Technologies, Inc., and Bio-Cell, Inc. (collectively "Viacell") filed an answer to PharmaStem's motion, and on August 15, 2003, PharmaStem filed a reply. The court conducted a pretrial conference on September 8, 2003 in which it heard oral argument from the parties on PharmaStem's motion. Upon consideration of the arguments raised at the pretrial conference and in the parties' briefs, the court will grant PharmaStem's motion *in limine*. The EPO Decision is not admissible evidence. The court bases its ruling on the following reasons.

II. DISCUSSION

The EPO Decision revokes PharmaStem's European patent that is related to its '681 patent presently at issue. The decision applies European, as opposed to United States, patent laws, and examines different claims than the ones at issue in this case. In the opinion, the EPO cites a 1997 article written by Hal Broxmeyer (the "Broxmeyer Article"), one of the inventors of the patents-in-suit. Published nearly ten years after the initial filing of the patents-in-suit, the Broxmeyer Article is not a prior art reference. The EPO cited the Broxmeyer Article for the proposition that the relevant scientific community considered progenitor cell assays to be reliable assays for stem cells. In addition, the EPO found that Koike, a prior art reference that PharmaStem also cited to the PTO, discloses stem cells.

The EPO Decision was published on July 21, 1999. A little over eight months later, the United States Patent and Trademark Office ("PTO") finished a near seven-year reexamination proceeding of PharmaStem's '681 patent and issued the reexamination certificate on April 11, 2000. Before the EPO Decision came out, PharmaStem argued to the PTO during the reexamination proceedings that Koike did not teach stem cells. In the intervening time period between the EPO Decision and the PTO's reissue of the '681 patent, PharmaStem did not cite the Broxmeyer Article to the PTO. Nor did PharmaStem disclose to the PTO the EPO's finding that the Koike reference teaches stem cells.

Viacell claims that the EPO Decision is relevant to these proceedings because it illustrates the materiality of the Broxmeyer Article and therefore supports Viacell's argument that PharmaStem engaged in inequitable conduct by failing to disclose the article to the PTO. Viacell further contends that the EPO's factual findings regarding the Koike reference may have been

important to a reasonable patent examiner in deciding whether to reissue the patents-in-suit. According to Viacell, the EPO Decision therefore must be admitted into evidence so that the jury may evaluate the EPO's factual determination that Koike discloses stem cells. Finally, Viacell claims that the EPO's finding of invalidity is relevant to its defense against PharmaStem's willful infringement claim because it confirms the reasonableness of the opinions of counsel upon which some of the defendants in this case relied. The court disagrees.

The EPO Decision cites the Broxmeyer Article in the portion of its opinion on novelty. The relevant language of the opinion states, "It appears undoubtful to the Opposition Division that there is a broad consensus in the scientific community as to the reliability of surrogate assays for progenitors, such as assays for CFU-GM, as indirect evidence for the presence of stem cells in a sample, as shown for example by the patent itself (paragraphs 6.6.3 and 6.8) and other documents, e.g., D21, D143 [the Broxmeyer Article] and D145." Decision Revoking the European Patent (Article 102(1) EPC) at 22. The EPO's mention of the Broxmeyer Article in this regard, at best, marginally supports Viacell's position that the Broxmeyer Article is material information. Indeed, the EPO itself refers to the article as an example of "indirect evidence"and cites it merely to refute PharmaStem's argument that progenitor cell assays were not predictive of the presence of stem cells.[1]

Similarly, the fact that the EPO Decision cited the article in this particular context has very little bearing on the issue of PharmaStem's intent to deceive the PTO. Applicants do have a duty to disclose to the PTO "any material prior art or other information cited or brought to their attention in any related foreign application." Manual of Patent Examining Procedure § 2001.06(a)

[1] Notably, the index of the EPO Decision lists at least 140 references.

(4th ed., rev. 8, Oct. 1981). However, a finding of inequitable conduct for nondisclosure of information requires proof that the applicant made a deliberate decision to withhold a known material reference from the PTO. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995). Given the EPO's peripheral reliance on the Broxmeyer Article, the relatively short period of time between the EPO and PTO decisions, and the fact that the Broxmeyer Article is not a prior art reference to the patents-in-suit, the EPO Decision has little probative value suggesting that PharmaStem thought the Broxmeyer Article was material and deliberately failed to disclose it to the PTO.

The EPO Decision's probative value is further diminished in view of the high standard of proof required to establish inequitable conduct. "One who alleges inequitable conduct arising from a failure to disclose prior art must offer clear and convincing proof of the materiality of the prior art, knowledge chargeable to the applicant of that prior art and of its materiality, and the applicant's failure to disclose the prior art, coupled with an intent to mislead the PTO." *Molins*, 48 F.3d at 1178; *accord Rockwell Techs., LLC v. Spectra Physics Lasers, Inc.*, 2002 WL 531555, at *3 (D. Del. Mar. 26, 2002). "Materiality and intent to deceive are distinct factual inquiries, and each must be shown by clear and convincing evidence." *Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1324 (Fed. Cir. 2000); *accord Isco Int'l, Inc. v. Conductus, Inc.*, 2003 WL 22006253, at *6 (D. Del. Aug. 21, 2003). The fact that the EPO cited the Broxmeyer Article under the described circumstances does little to carry Viacell's heavy burden.

Viacell relies on *Molins* for the proposition that PharmaStem's failure to cite the Broxmeyer Article to the PTO after the EPO referred to it constitutes evidence of inequitable conduct requiring admission of the entire EPO Decision. This reliance is misplaced. The

circumstances of *Molins* are distinguishable from the present situation. First, unlike the Broxmeyer Article, the reference at issue in *Molins* was prior art. *See id.* at 1180. Second, PharmaStem argued the validity of its patents to the PTO before the EPO decision came out. In sharp contrast, the patentee in *Molins* had amended and distinguished its claims around the prior art reference to several foreign patent offices over the course of thirteen years but never disclosed that reference to the PTO. *See id.* These distinctions are significant.[2] In this light, the probative value the EPO Decision on the issue of PharmaStem's intent to deceive is outweighed by the substantial risk that admitting the opinion would unfairly prejudice PharmaStem and confuse the jury.

Federal Rule of Evidence 403 gives the court broad discretion to exclude evidence where "its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." F.R.E. 403; *see, e.g., Betterbox Comms. Ltd. v. BB Techs., Inc.*, 300 F.3d 325, 330 (3d Cir. 2002) (emphasizing the district court's broad discretion when ruling on a Rule 403 request). An opinion, although of a quasi-judicial or administrative body and albeit that of a foreign jurisdiction, carries with it a certain imprimatur, which creates a substantial risk that the jury will give its conclusions undue deference. Even if the jury is instructed to consider the opinion for its limited purposes, there is a strong likelihood that the jury would be confused as to its relevance. Thus, the EPO's citation to the Broxmeyer Article in a string of exemplary documents

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[2] Likewise, the circumstances surrounding this court's decision in *Rockwell* were also vastly distinguishable from the present facts. In *Rockwell*, the alleged material information was also prior art and the patentee had similarly distinguished the references to two different foreign patent offices without disclosing them to the PTO. *Rockwell*, 2002 WL 531555, at *3. Based on those facts, the court determined that genuine issues of material fact existed with regard to the patentee's inequitable conduct. *Id.* at *4.

supporting its conclusion on one issue relating to novelty is not grounds for admitting the entire decision, particularly where less prejudicial means of making its argument are available to Viacell. Indeed, Viacell can make its argument that the Broxmeyer Article is material and that PharmaStem knew of its existence by submitting the article itself into evidence.

Viacell's remaining arguments for the admissibility of the EPO Decision also lack merit. The fact that EPO found that the Koike reference discloses stem cells does not render the entire opinion admissible. It is the role of the jury to make its own factual findings, not to rely on the factual findings of a foreign patent office. Again, Viacell can submit the Koike reference itself into evidence and argue its teachings to the jury.

The EPO Decision's relevance to Viacell's defense to PharmaStem's willful infringement claim also lacks the degree of probative value that would outweigh the opinion's substantial risk of jury confusion and prejudice to PharmaStem. Viacell argues that the EPO's revocation of the related patent confirms the reasonableness of opinions of counsel relied upon by some of the defendants in this case. The opinions of counsel themselves are admissible evidence. Introducing the EPO Decision to buttress these opinions, therefore, would be cumulative, confusing to the jury, and unfairly prejudicial to PharmaStem.

III. CONCLUSION

The court finds the EPO Decision's probative value to be substantially outweighed by the risk of unfair prejudice to PharmaStem and the likelihood of jury confusion. Because Viacell could accomplish a substantially similar and less prejudicial result by admitting the Broxmeyer Article, the Koike reference, and the legal opinions of counsel themselves, the court will exercise its discretion to exclude the EPO Decision from evidence.

Therefore, IT IS HEREBY ORDERED that:

1. PharmaStem Therapeutics, Inc.'s Motion *In Limine* to Exclude Decision of the European Patent Office From Evidence is GRANTED.

2. Viacell may not introduce the July 21, 1999 Decision of the European Patent Office into evidence.

Dated: September 30, 2003

Gregory M. Sleet
UNITED STATES DISTRICT JUDGE